DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Apotex Corp.
Attention: Marcy Macdonald
50 Lakeview Parkway, Suite 127
Vernon Hills, IL 60061

SEP 16 1999

Docket No. 98P-0858/CP1

Dear Ms. McDonald:

This is in response to your petition filed on September 30, 1998, and your amendments dated January 15, 1999, and March 11, 1999, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Cyclosporine Tablets 25 mg, 50 mg, and 100 mg. The listed drug products to which you refer in your petition are Neoral® (Cyclosporine) Capsules, 25 mg, 50 mg, and 100 mg manufactured by Novartis Pharmaceuticals Corp.

We have reviewed your petition under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act) and have determined that it is approved. This letter represents the Agency's determination that an ANDA may be submitted for the above-referenced drug products.

Your request involves a change in dosage form from that of the listed drug products (i.e., from capsule to tablet). The change you request is the type of change that is authorized under the Act.

Under Section 505(j)(2)(C)(i) of the Act, the Agency must approve a petition seeking a dosage form which differs from the dosage form of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing dosage form. The Agency finds that the change in dosage form for the specific proposed drug products does not pose questions of safety or effectiveness because the uses, dose, and route of administration of the proposed drug products are the same as that of the listed drug products.

In addition, this petition was evaluated with respect to the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs, and Biological Products in Pediatric Patients; Final Rule, published December 2, 1998, iri the Federal Register (Pediatric Rule)(63 FR 66632). The agency has determined that your proposed change in dosage form is subject to the Pediatric Rule and has concluded that investigations are not necessary to demonstrate the safety and effectiveness of your proposed product in the pediatric population, because the product is adequately labeled for the approved indications,

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The Agency concludes, therefore, that investigations are not necessary in this instance. The pediatric study requirement is waived at this time but may be reevaluated if new information is available at the time you file your application. In addition, if shown to meet bioavailability requirements, the proposed drug products can be expected to have the same therapeutic effect as the listed reference drug products.

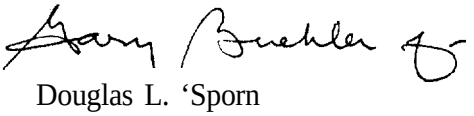
The approval of this petition to allow an ANDA to be submitted for the above-referenced drug products does not mean that the Agency has determined that an ANDA will be approved for the drug products. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the Agency.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug products will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you contact the Director, Division of Bioequivalence, at (301) 827-5847 to determine the specific requirements for these drug products. During the review of your application, the Agency may require the submission of additional information.

The listed drug products to which you refer in your ANDA must be the drug products upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission,

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,



Douglas L. 'Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research